K080320

FEB 21 20..

NDS
SURGICAL · IMAGING

510(k) SUMMARY

A. Manufacturer:	NDS Surgical Imaging, LLC 5750 Hellyer Avenue San Jose, CA 95138 USA
B. Submitted By:	Jim Leng Regulatory Engineer NDS Surgical Imaging, LLC
C. Date of Preparation:	Oct. 15, 2007
D. Contact Information:	Tel: 408-776-0085 Fax: 408-776-9878
E. Classification:	System, image processing, radiological
F. Common Name:	Monitor, display, and others
G. Proprietary Name:	PrimeVue 21" 3MP Color Display
H. Classification Number:	21 CFR 892.2050/Procode 90LLZ
I. Substantial Equivalence:	Coronis, Mdnc 3120 (Barco) K061927 RadiForce R31-C (Eizo Nanao) K052344
J. Device Description:	The PrimeVue 21 inch 3MP Color Display is a diagnostic display.
K. Intended Use:	The PrimeVue 21 inch 3MP Radiological Medical Display is intended to be used to display and view digital images for review and analysis by trained medical practitioners. However, This device must not be used in primary image diagnosis in mammography.
L. Technological Characteristics:	The PrimeVue 21 inch 3MP Display is a high-resolution Liquid Crystal Display (LCD) with electronic capabilities used for the review and analysis of high-resolution medical images by trained medical practitioners.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2008

NDS Surgical Imaging, LLC
c/o Mr. Tamas Borsai
Manager, Medical Division
TÜV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K080320
Trade/Device Name: PrimeVue 21" 3MP Radiology Medical Display
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 28, 2008
Received: February 6, 2008

Dear Mr. Borsai:

This letter corrects our substantially equivalent letter of February 21, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all

the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

NDS
SURGICAL · IMAGING

Indications for Use

510(k) Number (if known): N/A

Device Name: PrimeVue 21" 3MP Radiology Medical Display

Indications for Use:

The PrimeVue 21 inch Radiological Medical Display is intended to be used to display and view digital images for review and analysis by trained medical practitioners.

Prescription Use _X_ AND/OR Over-the-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIE LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080320